

Creating Establishment Registration SPL Documents

Basic instructions for creating
technically valid Establishment
Registration SPL Documents

Version 1.0

Use SPL Starter Package

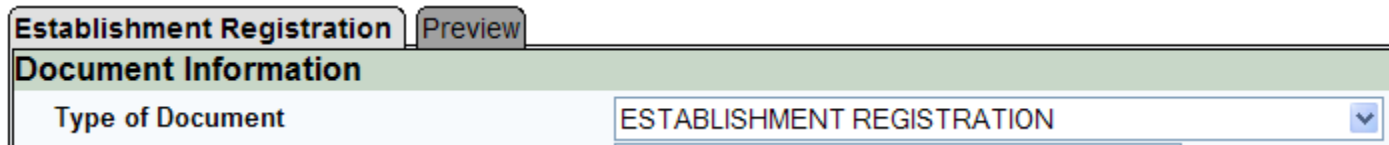
- Link to SPL Starter Package is located under the heading "Resources" on this web page:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Accessing the Establishment Registration SPL Xforms

- Open Establishment Registration SPL document Xforms file
“SPLForm_Registration.xhtml” (or equivalent in your SPL authoring software.)

Selecting Document Type

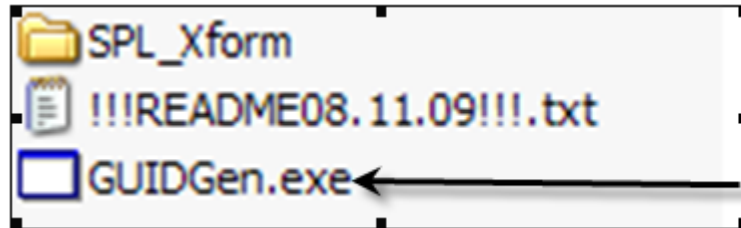


The screenshot shows a web form with two tabs: 'Establishment Registration' and 'Preview'. The 'Establishment Registration' tab is active. Below the tabs is a section titled 'Document Information'. Within this section, there is a label 'Type of Document' and a corresponding drop-down menu. The drop-down menu is open, showing the selected option 'ESTABLISHMENT REGISTRATION'.

Document Information	
Type of Document	ESTABLISHMENT REGISTRATION

- Select “Establishment Registration” from the drop-down menu.

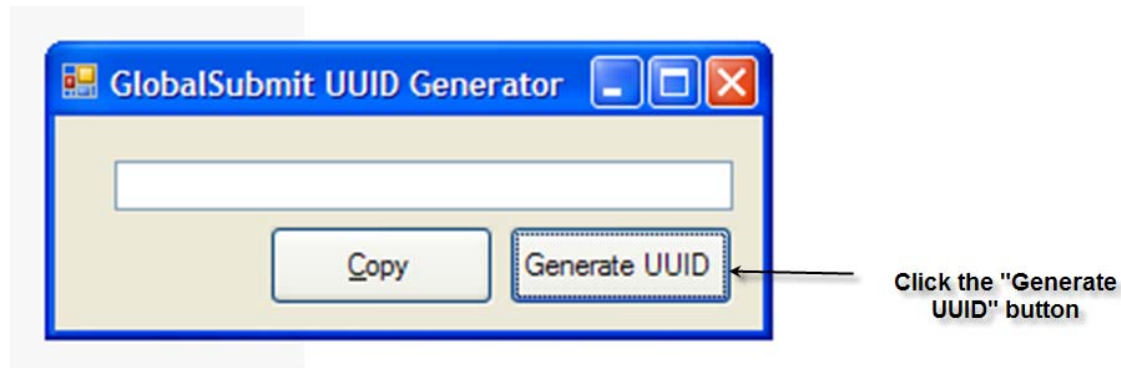
Generating GUIDs for IDs



Use the **GUID** generator executable file
or online version

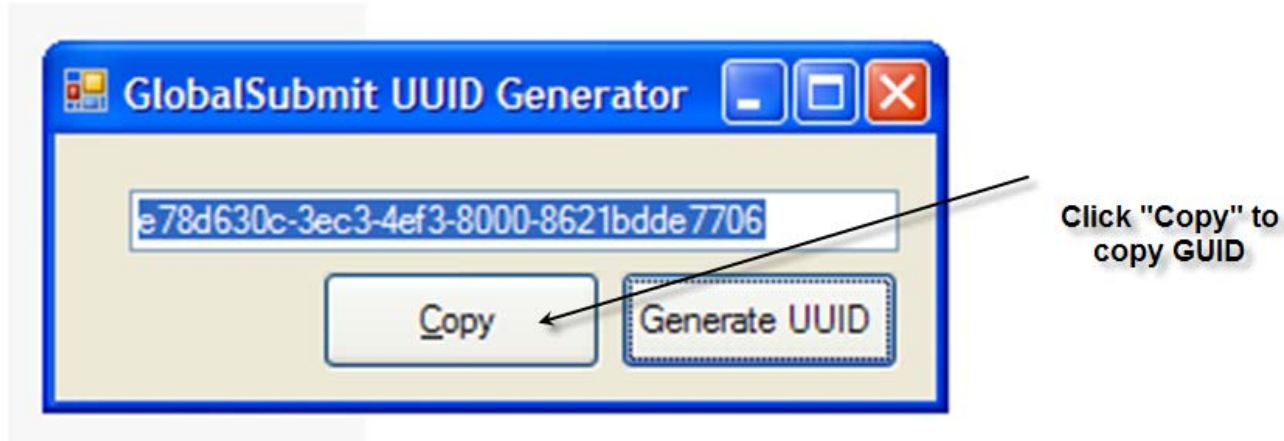
- Locate the Globally Unique Identifier (GUID) generator in the folder containing the SPL Xforms. GUIDs are also referred to as Universal Unique Identifiers (UUIDs)
- Double click executable file named “GUIDGen.exe.”
- If this program is incompatible with your PC, then search for an “online GUID generator” via your internet browser.

Generating GUIDs for IDs cont...



- Generate a GUID by choosing the “Generate UUID” button (or equivalent in online GUID generator tool.)

Generating GUIDs for IDs cont...



- Copy a GUID by choosing the “Copy” button (or equivalent in online GUID generator tool.)

Adding a SPL Document ID

ID	de706462-2e10-422f-9659-b42348c4c6ab
----	--------------------------------------

- Paste GUID in “ID” field
- The id root uniquely identifies a specific SPL file. Each new version of an SPL file has a new id root. The id root is a Globally Unique Identifier (GUID).
- Hereafter, the “id root” will be referred to as “ID” in this eBook.

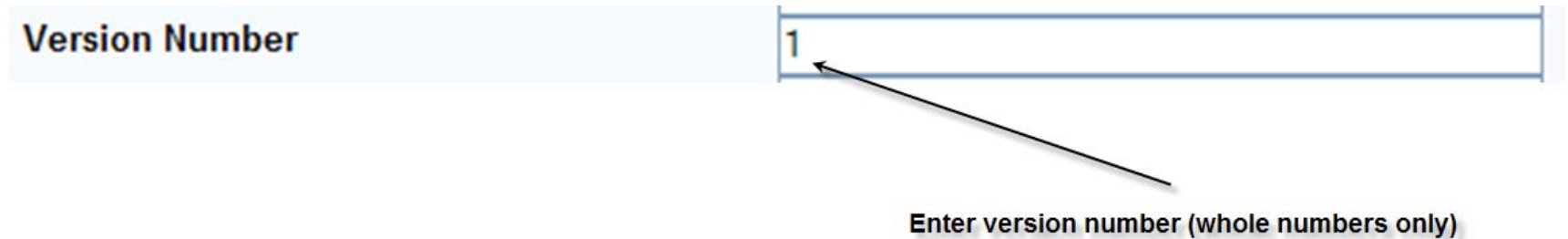
Assigning a Set ID

Set ID

e8684f7e-2422-4559-9305-3900fa8078ce

- Generate and copy another GUID using the GUID generator.
- Paste this GUID in the “Set ID” field.
- The setID root uniquely identifies a group of versions of an SPL file.

Version Number



A form with a light blue header bar containing the text "Version Number". Below the header is a white input field with a blue border. The number "1" is entered in the field. An arrow points from the text "Enter version number (whole numbers only)" below the field to the input field.

Version Number

1

Enter version number (whole numbers only)

- Enter a version number.
- The version number must be a whole number greater than zero.
- No spaces should be included before or after the version number.

Entering a Document Date

Effective Time	20090920
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Enter approximate submission date



- Enter a document date (Effective Time)
- Ensure that there are no spaces (created w/space bar) before or after date.
- The effective time provides a date reference to the SPL version. The date includes the year, month and day using the format yyymmdd.

Entering the Registrant's Name

Registrant	
Name	<input type="text" value="Acme Manufacturing"/>

- Type in the name of the registrant.
- The registrant is the owner/operator of the drug establishment(s)
- Enter the **headquarters business name** of the registrant registering the establishment(s).

Registrant's DUNS Number

Registrant

Name

Acme Manufacturing

DUNS Number

246396321

Enter DUNS Number for the Registrant

- Type the DUNS Number for the registrant's headquarters location.
- DUNS Numbers consist of **nine** digits
- Ensure **no hyphens** are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number

Registrant Contact's Name

Registrant Contact	
Name	Tammy Jamison

- Enter the first name and last name of contact person.
- The registrant contact is the person FDA contacts regarding the establishment registration information.

Registrant Contact Person's Address

Mailing Address

5892 Bayview Road

- Enter the street and number of the mailing address for the registrant contact person.

Enter City

City	Silver Spring
------	---------------

- Enter the city for the mailing address for the registrant contact person

Enter State or Province

State	MD
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- Enter the state for the mailing address for the registrant contact person. (Use state abbreviation)
- If there is no state, as with certain addresses outside the United States, leave the field empty.
- Provinces can be entered in the state field.

Entering Country Code

Country

USA

- Enter the **three-character** character country code using the ISO 3166-1 standard for the mailing address for the contact person.
- Do not include spaces (created w/space bar) before or after country code.
- Link to country code lists:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162567.htm>

Postal Codes

Postal Code	20993
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- Enter the postal code for the mailing address for the contact person.
- If there is no postal code, as with certain addresses outside the United States, leave the field empty.

Registrant Contact's Telephone Number

Telephone Number

tel:+1-525-293-1111

- Enter the telephone number for the contact person.
- Ensure that there are no spaces (created w/space bar) before or after telephone number.
- Telephone numbers are global telephone numbers using the Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966 (no letters; begin with “+”; **include hyphens to separate the country code, area codes and subscriber number**; extensions are separated by “;ext=”).

Registrant Contact's E-mail

Email Address

mailto:tammy.jamieson@acme.com

- Enter the email address for the contact person.
- Ensure that there are no spaces (created w/space bar) before or after e-mail address.

Registering a Drug Establishment

- Each Registrant (owner/operator firm) should submit one SPL file with registration information for all of its facilities
- There can be an unlimited amount of domestic or foreign establishments per file.

Entering the Establishment's Name


Establishment	
Name	Acme Manufacturing

- Enter the name of the drug establishment.

Establishment's DUNS Number

Establishment	
Name	Acme Manufacturing
DUNS Number	111825912

Enter establishment DUNS Number



- Type the DUNS Number for the establishment.
- The DUNS Number is site specific.
- Each establishment should have it's own DUNS Number.
- Ensure no hyphens are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number

FEI Number

Establishment

Name	Acme Manufacturing
DUNS Number	111825912
FEI	3003281921

Click "Add FEI" button only if you have an FEI number for this drug establishment.

If you accidentally select "Add FEI" number, then delete field by selecting "Delete FEI" button.

- If an FEI number is assigned for this site, then enter the FEI Number.
- FEI numbers are 7- or 10-digit number. Use leading zeros if necessary.
- If an FEI number is not assigned, **DO NOT** select "Add FEI" button. Delete FEI number field if there is no FEI #.

Establishment's Address

Mailing Address

5892 Bayview Road

- Enter the street and number of the mailing address for the establishment's physical address
- Ensure that it matches the address associated with the DUNS Number.

Enter City

City	Silver Spring
------	---------------

- Enter the city for the mailing address for establishment.
- Ensure that it matches the address associated with the DUNS Number.

Enter State or Province

State

MD

- Enter the state for the mailing address for the registrant contact person. (Use state abbreviation)
- If there is no state, as with certain addresses outside the United States, leave the field empty.
- Provinces can be entered in the state field.
- Ensure that it matches the address associated with the DUNS Number.

Entering Country Code

Country

USA

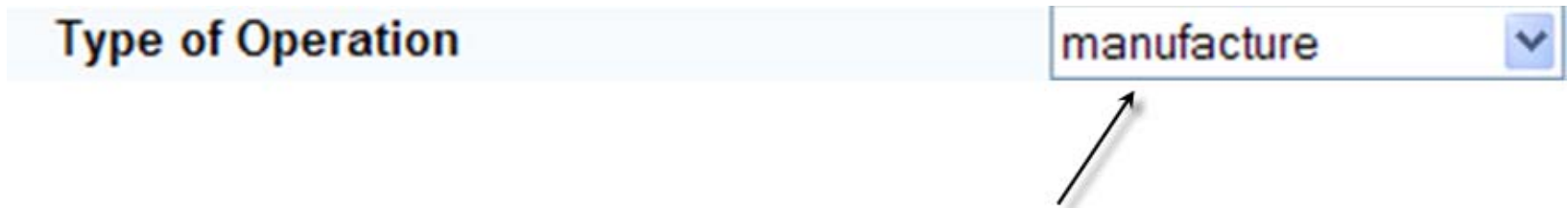
- Enter the **three-character** character country code using the ISO 3166-1 standard for the mailing address for the contact person.
- Do not include spaces (created w/space bar) before or after country code.
- Ensure that it matches the address associated with the DUNS Number.
- Link to country code lists:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162567.htm>

Postal Codes

Postal Code	20993
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- Enter the postal code for the mailing address for the contact person.
- If there is no postal code, as with certain addresses outside the United States, leave the field empty.
- Ensure that it matches the address associated with the DUNS Number.

Type(s) of Operation for Establishments



The image shows a screenshot of a web form. On the left, there is a light blue rectangular box with the text 'Type of Operation' in a dark font. To the right of this box is a drop-down menu. The menu is currently open, showing the word 'manufacture' in a dark font. To the right of the menu is a small blue square button with a white downward-pointing arrow. A black arrow points from the text below to the 'manufacture' option in the menu.

Choose type of operation from drop-down menu.
DO NOT use "United States Agent" or "Import" as the type of operation for an Establishment type of operation.

- Enter the **one or more drug manufacturing and processing operations** performed at the establishment.
- **DO NOT** use "UNITED STATES AGENT" or "IMPORT" as a type of operation for an establishment.

Establishment Contact Person's Name

Establishment Contact

Name

Keri Reed

- The contact is the person FDA contacts regarding the drug establishment.
- Enter the contact person's name in the name field.

Contact Person's Address

Mailing Address

788 Turnbelt Drive

- Enter the street and number of the mailing address for the contact person.

Enter City Name

City	Youngstown
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- Enter the city for the mailing address for the contact person

Enter State or Province

State

MD

- Enter the state for the mailing address for the contact person. (Use state abbreviation)
- If there is no state, as with certain addresses outside the United States, leave the field empty.
- Provinces can be entered in the state field.

Entering Country Code

Country	<input type="text" value="USA"/>
---------	----------------------------------

- Enter the **three-character** character country code using the ISO 3166-1 standard for the mailing address for the contact person.
- Do not include spaces (created w/space bar) before or after country code.
- Link to country code lists:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162567.htm>

Postal Codes

Postal Code	<input type="text" value="20851"/>
-------------	------------------------------------

- Enter the postal code for the mailing address for the contact person.
- If there is no postal code, as with certain addresses outside the United States, leave the field empty.

Contact Person's Telephone Number

Telephone Number

tel:+1-888-582-5221

- Enter the contact telephone number for the contact person.
- Ensure that there are no spaces (created w/space bar) before or after telephone number.
- Telephone numbers are global telephone numbers using the Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966 (no letters; begin with “+”; **include hyphens to separate the country code, area codes and subscriber number**; extensions are separated by “;ext=”).

Contact Person's E-mail address

Email Address

mailto:keri.reed@acme.com

- Enter the email address for the contact person.
- Ensure that there are no spaces (created w/space bar) before or after e-mail address.

US Agent

Add United States Agent

Delete United States Agent

- If the establishment is located **outside the US**, provide information about the US agent for that foreign drug establishment.
- Select “Add United States Agent” to reveal fields for US agent data.
- Use “Delete United States Agent” if US agents fields are not needed.

US Agent Name

United States Agent	
Name	<input type="text" value="US Agents Inc."/>

- Enter the **business** name of the US agent.
- Do not enter person's name in this field unless name is the same as business name.

US Agent's DUNS Number

United States Agent	
Name	US Agents Inc.
DUNS number	885928192

Enter DUNS Number for US Agent

- Type the DUNS Number for the US Agent's location.
- Ensure no hyphens are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number

US Agent's Telephone Number

United States Agent

Name

US Agents Inc.

DUNS number

885928192

Telephone Number

tel:+1-888-999-5821

Enter the telephone number

- Enter the US agent's telephone number.
- Ensure that there are no spaces (created w/space bar) before or after telephone number.
- Telephone numbers are global telephone numbers using the Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966 (no letters; begin with “+”; **include hyphens to separate the country code, area codes and subscriber number**; extensions are separated by “;ext=”).

US Agent's E-mail Address

United States Agent	
Name	US Agents Inc.
DUNS number	885928192
Telephone Number	tel:+1-888-999-5821
Email Address	mailto:sarah.peterson@usagents.com
<input type="button" value="Add United States Agent"/> <input type="button" value="Delete United States Agent"/>	

Enter e-mail address

- Enter the email address for the US agent.
- Ensure that there are no spaces (created w/space bar) before or after e-mail address.

Adding the Importer



- To add importer information, select the “Add Importer” button.
- Choose “Delete Importer” if fields are not to be populated.
- May or may not be an importer for each foreign establishment
- Unlimited amount of importers can be included for each foreign establishment.

Importer's Name

Importer	
Name	Franklin Imports

- Enter the **business** name of the importer.
- Do not enter person's name in this field unless name is the same as business name.

Importer's DUNS Number

Importer	
Name	Franklin Imports
DUNS number	222258192

Enter importer's DUNS Number

- Enter the DUNS Number for the importer's location.
- Ensure no hyphens are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number

Importer's Telephone Number


Importer	
Name	Franklin Imports
DUNS number	222258192
Telephone Number	tel:+1-800-582-9521

Enter telephone number

- Type the DUNS Number for the importer's location.
- Ensure no hyphens are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number

Importer's E-mail

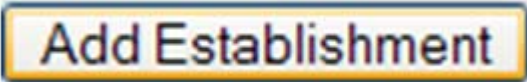
Importer	
Name	Franklin Imports
DUNS number	222258192
Telephone Number	tel:+1-800-582-9521
Email Address	mailto:paul.franklin@franklin.com



Enter e-mail address

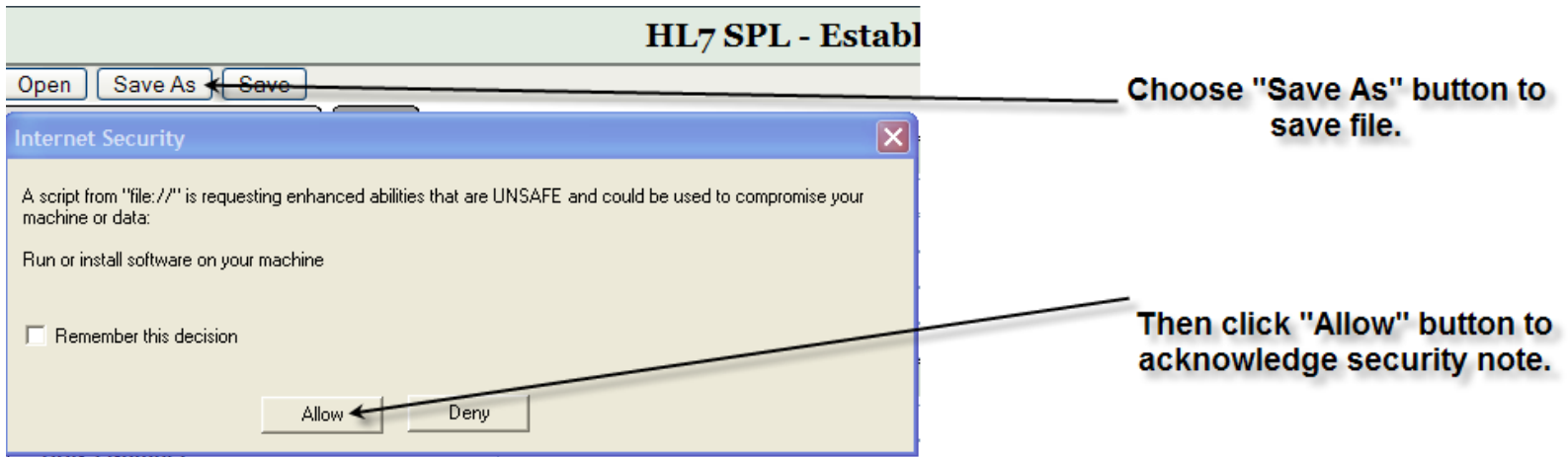
- Enter the email address for the importer.
- Ensure that there are no spaces (created w/space bar) before or after e-mail address.

Additional Establishments

A rectangular button with a yellow border and a light yellow background, containing the text "Add Establishment" in a dark blue font.A rectangular button with a blue border and a light blue background, containing the text "Delete Establishment" in a dark blue font.

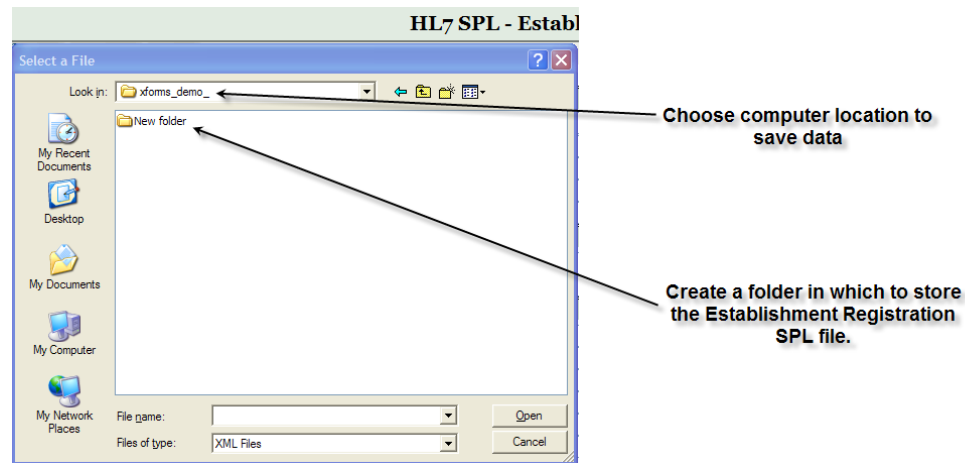
- To add additional drug establishments to the file, select “Add Establishment” and proceed with entering information for your other drug establishments.
- Use preceding slides as guide for entering data.

Saving the File



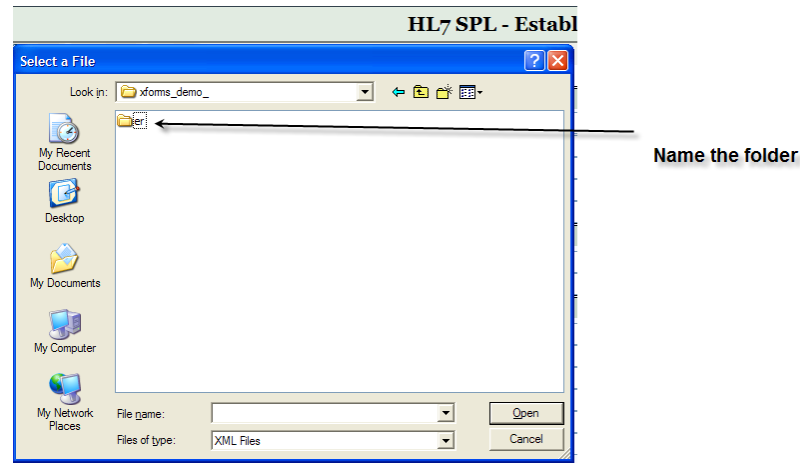
- When saving the SPL file for the first time, select the “Save As” button.
- Then select the “Allow” button to continue saving.
- You can check “Remember This Decision” checkbox to avoid future security prompts.

Creating the Submission Folder



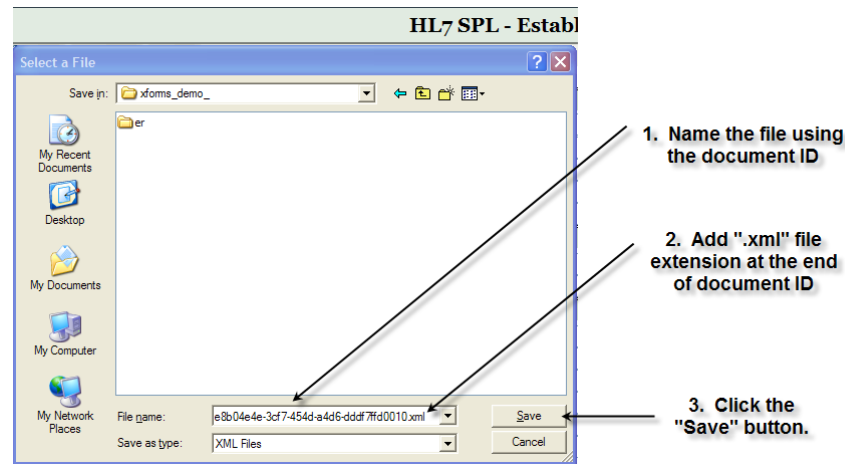
- Choose computer location in which to store folder to contain the SPL file.
- Create a folder in which to store the Establishment Registration SPL file.

Naming the Submission Folder



- There is no folder naming convention
- However, we recommend that you not use symbols in the name of the folder.

Naming the SPL File



- Use the **document ID** (GUID) as the document file name
- Use ".xml" as the file extension
- Choose "Save" button
- If you do not follow these steps your SPL will **FAIL** validation.

Establishment Registration

- Navigate to computer location and double click the SPL file icon to open file.
- If you can not view the file, then neither can FDA.
- Send File to FDA via FDA “OC” Gateway
- See screenshot of the SPL view of an example of an Establishment Registration SPL document on next slide.

Establishment Registration SPL

Product Information	
Product Type	ESTABLISHMENT REGISTRATION

Registrant - Acme Manufacturing (246396321)			
Contact	Address	Telephone Number	Email Address
Tammy Jamison	Address: 5892 Bayard Road City, State, Zip: Silver Spring, MD, 20993 Country: USA	+1-525-293-1111	tammy.jamieson@acme.com

Establishment			
Name	Address	ID/FEI	Operations
Acme Manufacturing	Address: 788 Turnbelt Drive City, State, Zip: Youngstown, MD, 20851 Country: USA	111825912/3003281921	manufacture
Contact	Address	Telephone Number	Email Address
Keri Reed	Address: 788 Turnbelt Drive City, State, Zip: Youngstown, MD, 20851 Country: USA	+1-888-582-5221	keri.reed@acme.com

Revised: 12/2009

Need More Detailed Instructions?

- Use Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for Drug Establishment Registration and Drug Listing
- This document is located on the SPL Resources web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Test Your SPL R4 Submissions

- Use Pragmatic Data Validator Lite to test your SPL files prior to transmission to FDA:

<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>

Submitting Files via FDA Gateway

WebTrader Help Logout

Send document

Select who will receive the document

Gateway: FDATST

Center: **Select the "OC" center**

Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path: **Browse...** **Ensure that you are submitting SPL in a folder (file name should not appear in the path field)**

Root directory: **Browse...**

Submission type: **Select "SPL" as the submission type**

Select a signing certificate

Current file: M:\SPL_Main\gateway\Lonnie Smith\Lonnie Smith.p12

New file: **Browse...**
MyCertificate.p12 or MyPrivateKey.pfx

Send

Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov link. Below is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a 'Sign up for email updates.' link with an arrow pointing to it. Below this is a paragraph about the council's mission and a link to 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

FDA Resources for Standards

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

SPL-related Technical Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)